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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
YUKINO OWAKI, ET AL.	: EXAMINER: GOLLAMUDI, S.
SERIAL NO: 09/786,370	:
FILED: MARCH 15, 2001	: GROUP ART UNIT: 1616
FOR: TAPE MATERIAL FOR TRANSCUTANEOUS ABSORPTION	:

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Naomi Ikeda who deposes and states that:

1. I am familiar with the invention claimed in the above-identified application.

2. I am a graduate of Sasebo National College of Technology ~~and received a~~ N.I. Jan. 11. 2005 Industrial Chemistry department ~~degree~~ in the year 1979.

3. I have been employed by Yutoku Pharmaceutical Ind. Co., Ltd., since 1979 and I have been conducting research in the field of Transdermal absorption preparation for 16 years.

4. I have reviewed and understood the contents of JP10-147521 which is cited by the Examiner as prior art against the claims of the above-identified application. In order to provide a side-by-side comparison of compositions which meet the present claim limitations against a composition which is disclosed in JP10-147521, the following experiments were carried out by me or under my direct supervision and control.

1. Production of preparations to be tested

In accordance with the formulation shown below, the butyl-rubber-containing tape preparation of Example 2 disclosed in the specification of the subject application (hereinafter referred to as "the invention preparation") and tape preparations with butyl rubber contained in proportions of from 1% to 30%, respectively, were produced. Using them, the following test was conducted.

(Formulation)

	Invention prepn.	1% BR	15% BR	20% BR	30% BR
Lidocaine	10	10	10	10	10
SIS	25	25	15	15	10
Butyl rubber (BR)	5	1	15	20	30
Alicyclic saturated hydrocarbon resin	31	33	31	26	21
Liquid paraffin	24	26	24	24	24
Zinc oxide	5	5	5	5	5
Antioxidant	0.1	0.1	0.1	0.1	0.1

(parts by weight)

2. Applicability test

An applicability test was conducted on healthy adults (n=20). The preparations were each applied to the lateral region of the chest, which is a region showing relatively great skin movements. Upon elapsed times of 24 hours, 48 hours and 72 hours after the application, the preparations were observed for their conditions of adhesion. The results are shown in Table 1.

(Results)

Table 1 Results of Applicability Test

Test prepn.	Number of persons (out of 20) showing the conditions of adhesion defined below								
	24 hours after application			48 hours after application			72 hours after application		
	No turn up	Slight turn up	Drop-ping	No turn up	Slight turn up	Drop-ping	No turn up	Slight turn up	Drop-ping
Invention prepn.	20	0	0	20	0	0	18	2	0
1% BR	20	0	0	18	2	0	16	4	0
15% BR	20	0	0	20	0	0	18	2	0
20% BR	20	0	0	19	1	0	17	3	0
30% BR	20	0	0	18	2	0	15	5	0

As is evident from Table 1, all the preparations remained satisfactorily adhering on the skin and showed substantially no skin irritation until the 48th hour after the application. At the 72nd hour after the application, the 1% and 5% butyl rubber preparations still had good applicability although only slight turn up was observed. The 15%, 20% and 30% butyl rubber preparations had good applicability without any turn-up.

3. Stratum corneum abrasion test

Each preparation produced in Item 1 was examined for stratum corneum abrading property by applying it to the upper arm of each of healthy adults (n=5) and peeling it off 3 hours after the application. Each preparation removed was transcribed onto a measurement tape and, after washing it with ethanol for defatting, the stratum corneum was stained with a staining solution, followed by immersion in an aqueous solution of sodium dodecyl sulfate. The amount of the eluted staining substance was measured based on the absorbance data.

Since the absorbance is proportional to the amount of stratum corneum adhering on the preparation removed, the absorbance was regarded as the amount of abraded stratum corneum. The results are shown in Table 2.

(Results)

Tested preparation	Amount of abraded stratum corneum (absorbance Abs)
Invention preparation	0.127
1% BR	0.133
15% BR	0.130
20% BR	0.141
30% BR	0.152

Table 2 Amounts of Abraded Stratum Corneum

As is evident from Table 2, the invention preparation with 5% butyl rubber added therein and the preparations with 1% to 30% butyl rubber added therein were confirmed to be of substantially the same level in the amount of abraded stratum corneum.

In view of the above-described results in combination with the results of the previous comparison test on the 5% butyl rubber preparation and butyl-rubber-free preparations, the invention products are believed to be smaller in the amount of abraded stratum corneum and to have better applicability compared with the butyl-rubber-free preparations.

The above-described testing provides a basis for showing that the claimed tape preparation which may contain from 1-30% of a butyl rubber provides improvements in terms of adhesion and stratum corneum abrasion in comparison with the closest prior art and a comparative preparation not containing any butyl rubber.

5. The undersigned petitioner declares further that all statements made herein of ~~her~~ his own knowledge are true and that all statements made on information and belief are believed N.I. Jan. 11, 2005

to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing therefrom.

6. Further deponent saith not.

Naomi Ikeda

Naomi Ikeda

Jan. 11. 2005

Date